NSU Institutional Review Board/Ethics Review Committee

Review of a New Proposal Involving Human Subjects Research

Primary Reviewer Template *(see instructions on page three)*

IRB/ERC Review Code: 2020/OR-NSU/IRB-_____

Primary Reviewer: Designation:

Date of Review:

Initial Checklist: ***The Proposal document contains the following components:***

- ☐ Scientific Merit Review approval document included
- ☐ Summary of the protocol
- ☐ Detailed description of protocol procedures (with supporting materials)
- ☐ Consent Document

Proposed Study has had review for scientific merit *with approval*: ☐ Yes ☐ No
(if yes, identify school SRC and date of review approval; if not, discontinue review)

School SRC: ☐SHLS; ☐SEPS; ☐SHSS; ☐SBE; **Date of SRC Review:** _____

Purpose of Research Study:

Summary (Background, number of arms, controls, IND, etc.):

Sponsored Research: ☐ Yes ☐ No; *if "yes" identify sponsor(s):*
Name of Funding Agency:

PI/Co-PI(s): ☐ Qualified ☐ Not Qualified; **Experience is:** ☐ Adequate ☐ Inadequate

Conflict(s) of Interest: ☐ Yes ☐ No; if "yes," explain briefly below:

Study Population and Recruitment Practices:

1	
2	
3	
4	

Includes vulnerable research subjects (e.g., children, institutionalized population group, etc.): ☐ Yes ☐ No

Research subject recruitment is adequate: ☐ Yes ☐ No
(explain briefly who, where, how recruited):

Payment or reimbursements involved: ☐ Yes ☐ No

Subject selection is likely to be equitable: ☐ Yes ☐ No

Study has adequate procedures to protect vulnerable research subjects: ☐ Yes ☐ No

Informed Consent Document is adequate to the understanding of the research subjects: ☐ Yes ☐ No;
(*if "no" provide suggestions and/or questions for principal investigator below)*

Research subjects will be informed about research results: ☐ Yes ☐ No

Risk to research subjects is: ☐ minimal; ☐ moderate; ☐ high

Investigator's protocol minimizes risk to research subjects: ☐ Yes ☐ No

Potential benefits: ☐ Direct to research subjects; ☐ Indirect (altruistic)
If direct benefits to the research subjects explain briefly:

Risk/benefit analysis (risks to research subjects are minimized and reasonable in view of potential benefits identified): ☐ Yes ☐ No; *provide brief comments below:*

Eventuality plan in place in case of adverse event and/or serious adverse event: ☐ Yes ☐ No ☐ N/A

Confidentiality: Provisions to protect research subject privacy and confidentiality are adequate: ☐ Yes ☐ No

Data Oversight:

(a) There is adequate provision for data safety and monitoring: ☐ Yes ☐ No
(b) Rules for halting research are explained and sufficiently detailed: ☐ Yes ☐ No

Additional Comments:

Reviewer's Recommendation:

☐ Approved ☐ Disapproved ☐ Conditional Approval ☐ Waived

Signature of Primary Reviewer: _____

Basic Instructions to Primary Reviewer on Order of Review

1. *Read the consent document.*
   Note that the consent document should explain aspects of the study to potential research subjects in lay (not technical) language. It should provide a reasonably clear introduction to the research protocol. You should at this time read the document to orient yourself about the overall design of the research proposed.

2. *Read the protocol summary.*
   Read the summary and assure yourself that the investigator has summarized the important aspects of the study in a way that facilitates IRB full committee review.

3. *Read the full protocol and supporting material.*
   Read the protocol and supporting materials to understand with a view to prior studies that are applicable to the study and that validate the research procedures outlined in the protocol (e.g., animal model studies done; safety studies done; efficacy studies done; rationale for a human study; phased clinical trial information; etc.). Assess whether there is evidence of detailed inclusion/exclusion criteria being met, recruitment procedures including advertisements, etc.

4. *Read the consent document again.*
   On this second reading of the consent document, record any suggested corrections or questions for the principal investigator.